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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,396	03/12/2007	Avner Yayon	YAYON11	6136

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,396	YAYON, AVNER	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12,13,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12,13,27,28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/09 and 11/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The rejection of claims 14-26 for the reasons elaborated in paragraph 3 of the previous Office Action (Claims 14-26 provides for the use of the recited reagents, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.) is withdrawn in view of the cancellation of said claims.

4. The rejection of claims 14-26 for the reasons elaborated in paragraph 4 of the previous Office Action (Claims 14-26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966) is withdrawn in view of the cancellation of said claims.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejection of claims 1-5,11-18,24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as per enunciated in the previous Office Action is withdrawn as pertaining to the following section enunciated in the previous Office Action (Claim 1 recites a method that uses a FGFR 3 inhibitor. The term FGFR 3 inhibitor encompasses a potentially vast array of molecules which can function as inhibitors of FGFR 3 such as those recited in claim 2 wherein said molecules are not disclosed in the specification or known in the prior art (such as small organic molecules per se, peptide mimetics, nonprotein inhibitors, etc.) and wherein the structure of said molecules is unpredictable.) in view of the amended claims and cancellation of claims that have been cancelled.

7. Claims 1,3-5,12,13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed methods.

The claims encompass a method that uses an antibody which binds FGFR 3. The only FGFR 3 disclosed in the specification is FGFR 3 with the particular amino acid sequence disclosed in the specification. The term FGFR 3 encompasses a potentially vast array of unknown molecules and mutants of known molecules which are not disclosed in the specification or known in the prior art and wherein the structure of said molecules is unpredictable. Whilst human and murine FGFR 3 appear to have been known the art, the claims encompass use of antibody which binds FGFR 3 wherein the

FGRFR 3 is derived from any mammalian species wherein the identity of such molecules is unknown and unpredictable. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only
described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the

sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments about the specification, page 10, based on said definition, the term FGFR 3 encompasses a potentially vast array of unknown molecules and mutants of known molecules which are not disclosed in the specification or known in the prior art and wherein the structure of said molecules is unpredictable. Whilst human and murine FGFR 3 appear to have been known the art, the claims encompass use of antibody which binds FGFR 3 wherein the FGRFR 3 is derived from any mammalian species wherein the identity of such molecules is unknown and unpredictable. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. The rejection of claims 1,2,11,14,15,24-26 under 35 U.S.C. 102(b) as being anticipated by Yayon et al. (WO 00/27379) for the reasons elaborated in the previous Office action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

9. Claims 1,3-10,27,28 are rejected under 35 U.S.C. 102(e) or 102(a) as being anticipated by Yayon et al. (WO 02/102973) as evidenced by Kastelan et al.
Yayon et al. discloses use of antibody or antibody fragment against FGR3 to treat proliferative diabetic retinopathy (see page 29) wherein said disease is inherently a T cell mediated inflammatory disease (as evidenced by Kastelan, abstract, last sentence and in view of T cell involvement disclosed in the abstract). WO 02/10293 discloses the antibodies/antibody fragments recited in the claims (see Table 1a and pages 17-22). Yayon et al. teach that said medicament is used in a pharmaceutically acceptable carrier (see claims 1-6,11). Yayon et al. disclose that the antibody can bind FGFR3IIIb (aka the sequences recited in claims 27/28) (see Figure 10 and pages 27,29).

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1,3-10,12,13,27,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yayon et al. (WO 00/27379) in view of Yayon et al. (WO 02/102973)

Yayon et al. (WO 00/27379) teach a small organic molecule inhibitor of FGFR 3 which is a tyrosinase kinase inhibitor (see page 40, Example 11, claims 1-6,17) and use of said molecule to treat rheumatoid arthritis (see page 8, last paragraph). Yayon et al. (WO 00/27379) teach that said medicament is used in a pharmaceutically acceptable carrier (see claims 1-6,17). Yayon et al. (WO 00/27379) do not teach use of antibody against FGFR3 to treat said disease. Yayon et al. (WO 02/102973) discloses use of antibody or antibody fragment against FGR3 to treat disease wherein FGR3 is involved (see pages 28-30). WO 02/102973 discloses the antibodies/antibody fragments recited in the claims (see Table 1a and pages 17-22). Yayon et al. (WO 02/102973) teach that said medicament is used in a pharmaceutically acceptable carrier (see claims 1-6,11). Yavon et al. (WO 02/102973) disclose that the antibody can bind FGFR3IIIb (aka the sequences recited in claims 27/28) (see Figure 10 and pages 27,29). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Yayon et al. (WO 00/27379) teach a small organic molecule inhibitor of FGFR 3 and use of said molecule to treat rheumatoid arthritis whilst Yayon et al. (WO 02/102973) discloses use of antibody or antibody fragment against FGR3 to treat disease wherein FGR3 is involved. One of ordinary skill in the art would have been motivated to do the aforementioned because Yayon et al. (WO 00/27379) teach a small organic molecule inhibitor of FGFR 3 and use of said molecule to treat rheumatoid arthritis whilst Yayon et al. (WO 02/102973) discloses use of antibody or antibody fragment against FGR3 to treat disease wherein FGR3 is involved. In addition, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

12. Claims 1,3-5,12,13,27,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yayon et al. (WO 00/27379) in view of Cappellen et al. (WO 00/68424).

Yayon et al. (WO 00/27379) teach a small organic molecule inhibitor of FGFR 3 which is a tyrosinase kinase inhibitor (see page 40, Example 11, claims 1-6,17) and use of said molecule to treat rheumatoid arthritis (see page 8, last paragraph). Yayon et al. (WO 00/27379) teach that said medicament is used in a pharmaceutically acceptable carrier (see claims 1-6,17). Yayon et al. (WO 00/27379) do not teach use of antibody against FGFR3 to treat said disease. Cappellen et al. discloses use of antibody against the extracellular domain of FGFR3 or FGFRIIIb (aka sequences recited in claim 27/28) to treat disease wherein FGFR3 is involved (see page 1, first paragraph, page 2, second paragraph, page 4, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Yayon et al. (WO 00/27379) teach a small organic molecule inhibitor of FGFR 3 and use of said molecule to treat rheumatoid arthritis whilst Cappellen et al. discloses use of antibody or antibody fragment against the extracellular domain of FGFR3 or FGFRIIIb (aka sequences recited in claim 27/28) to treat disease wherein FGFR3 is involved. One of ordinary skill in the art would have been motivated to do the aforementioned because Yayon et al. (WO 00/27379) teach a small organic molecule inhibitor of FGFR 3 and use of said molecule to treat rheumatoid arthritis whilst Cappellen et al. discloses use of antibody or antibody fragment against the extracellular domain of FGR3 or FGFRIIIb (aka sequences recited in claim 27/28) to treat disease wherein FGR3 is involved.
In addition, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D
Primary Examiner, Art Unit 1644